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(54) Title: IMPROVED METHODS OF STRIP INSERTION DETECTION

(57) Abstract: A method an apparatus for strip insertion detection in an analytical meter system. The invention allows for individual meter calibration, adaptive thresholding and ambient light correction. Increased performance is economically realized, while providing enhanced meter accuracy in varying light conditions.

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IMPROVED METHOD OF STRIP INSERTION DETECTION

DESCRIPTION OF THE INVENTION

Field of the Invention

The present invention relates generally to methods of measuring the concentration of an analyte in a fluid sample. More particularly, this invention provides method and apparatus for detecting the presence of a test element, such as a dry chemistry strip, in a meter device.

Background of the Invention

Monitoring analytes such as glucose, cholesterol, intoxicants, and other constituents is frequently desirable in fluids, such as blood, plasma, blood serum, saliva, urine, and other biological fluids. In healthcare applications, such monitoring affords the opportunity to make rapid diagnoses of a patient's condition and to take prophylactic or therapeutic measures necessary for maintaining proper health.

One such healthcare application that has benefited tremendously by analyte monitoring in recent years is the treatment of diabetes. Diabetics suffer from an impaired ability to regulate glucose levels in their blood. As a result, diabetics can have abnormally high blood sugar levels known as hyperglycemia. Chronic hyperglycemia may lead to long-term complications such as cardiovascular disease and degeneration of the kidneys, retinas, blood vessels and the nervous system. To minimize the risk of such long term complications, diabetics must strictly monitor and manage their blood glucose levels.

Diabetics that have glucose levels that fluctuate several times throughout the day require very close blood glucose level monitoring. Close monitoring of blood glucose levels is most easily obtained when a diabetic is able to monitor their glucose levels themselves. Many devices currently available allow diabetics to measure their own blood sugar levels.

Reflectance-based monitors comprise one category of personal, or home-use, glucose level monitoring devices. These monitors utilize an optical block which accepts test elements for photometric analysis.

The test elements are usually in the form of test strips, which contain analytical chemistry. Conventionally, these test strips are in the form of a disposable diagnostic test strip containing analytical chemistry upon which a fluid sample is deposited. Once the user applies the fluid sample to the test strip, and the sample has sufficiently penetrated the test strip, a chemical reaction occurs in the presence of a target analyte, e.g., glucose, to cause a change in the optical properties of the test strip. An optical photometric device then determines the analyte level of the sample by measuring an optical property, such as the intensity of reflected light at a certain wavelength from the test strip. For in vitro analysis in healthcare applications, the fluid sample is usually fresh whole blood.

Diagnostic test strips for testing analytes such as glucose levels of blood samples are well known in the art and comprise various structures and materials. Test strips typically include single or multi-layered porous membrane arrangements which receive a blood sample and undergo a change in an optical property, such as a color

2

change, in response to the interaction of blood glucose with agents/reactants in the membrane. Examples of such multi-layer strips are described in U.S. Patents 5,296,192 to Carroll and 6,010,999 to Carroll et al., the contents of both of which are incorporated herein by reference.

Prior to reaching the reactants, a whole blood sample can be filtered to eliminate potential optical interference by removing erythrocytes, or red blood cells. Some test strips operate to allow the applied blood sample to migrate to a reaction site in the membrane where the sample reacts with the agents/reactants, which is located in downstream capillary relation to the sample application site. The results of the reaction are often visible as a color change at the reaction site. However, the change may occur in invisible regions of the electromagnetic spectrum, such as infrared and ultraviolet. For the purposes of this application, the term "color change" will be understood to include variations in optical properties throughout the visible and invisible regions of the electromagnetic spectrum. As noted above, a color change can be correlated to the amount of glucose in the sample. Home-use glucose measuring devices that use a reflectance meter to measure the color change of the test strip correlate glucose levels to the change in the amount of light reflected from the reaction site of the test strip. As is well known in the art, strips can be formulated to produce a color change within a certain spectral region, and the meter designed to photometrically measure reflected, absorbed or transmitted light at a wavelength sensitive to the color change of the strip. While the present invention will be described with reference to reflectance based

3

photometry, it would be known to one having ordinary skill in the art to apply the features of the invention to absorbance or transmittance based systems.

An important aspect to the accurate measurement of glucose levels in a fluid using a test strip are the methods used to calculate the glucose concentration values from the reflectance values obtained. Because different samples physically vary and will contain different levels of analyte, reaction rates and durations will vary. Prior art devices have focused on fixing an initiation point, the time from which the monitoring device begins to measure the chemical reaction of the blood sample with the test strip. This initiation point often was carefully tied to the initial contact of analyte and reagent, either manually or automatically and then the reaction was timed for a fixed period of time from this initiation point. The end point is the time at which the monitoring device takes a final reflectance reading to calculate the reported glucose level of the sample from calibration data stored in the meter's memory. Because a fixed time (or times) is used in the prior art, calibration is simplified, but this approach requires waiting for a fixed period. The fixed time period is usually longer than required for the reaction to complete, resulting in user inconvenience.

Some home-use glucose monitoring devices have an initiation point corresponding to manual, or user determined events. For example, some monitoring devices trigger the initiation point for measuring glucose levels upon the pressing of a button, the insertion of a test strip into the monitoring device, or upon closing an element, such as a cover or door, of the monitoring device over the test strip. These user-defined initiation points decrease the accuracy and consistency of the monitoring

4

device because they rely on the inconsistent timing of an action by the user (i.e. insertion or covering of the test strip in the monitoring device). These inaccuracies in determining the initiation point are commonly carried through to the end point measurement time. This results from the fact that many common monitoring devices use a fixed time period from the initiation point to determine when to initiate the end point measurement. This fixed period timing is especially problematic when using multilayer test strips because of the nonuniform absorption periods inherent with such test strips, owing to physical differences between various samples (e.g. hematocrit, sample viscosity, as well as general operating conditions such as humidity, temperature, etc.).

Accordingly, conventional methods for determining initiation and end points for measuring glucose levels from test strips may yield inaccurate results because the methods depend on events or time periods unrelated to the reaction kinetics of the blood sample and the test strip. Further, because reactions each occur at different rates, reliance on a fixed time period between an initiation point and the end point may prolong the measuring time beyond the time necessary to accurately measure the glucose level of the sample, resulting in user inconvenience. While a more accurate measuring time may only yield a few seconds improvement over a fixed measuring time, such an improvement is substantial to the person who uses a device multiple times daily. Further, a more accurate, uncomplicated and quick method for testing blood samples for glucose levels will encourage patients to monitor their blood sugar levels more regularly, thereby promoting compliance with their prescribed regimens for diabetes management. Such an improved method is described in commonly assigned

5

copending US Patent Application No. 09/____,____ (Atty Docket 0011-00000 entitled "Method for Determining the Concentration of an Analyte on a Test Strip"), filed concurrently herewith, the contents of which are incorporated herein by reference.

An endpoint seeking algorithm such as that described in the above patent application incorporated herein by reference begins when it is determined that an analytical element, e.g. a chemistry strip, has been inserted. A separate strip sensor signal is generated by a photo-reflective device or "strip sensor" when a sample that is above a certain reflectance, such as the white tip of a PRESTIGE strip, is placed in close proximity to the sensor.

In ordinary use, photo-reflective strip sensors of the type used herein simply generate a current that is roughly proportional to the reflectance of the sample which is in it's field of view. This current is converted to a suitably scaled voltage using an appropriate load resistor, and if this voltage is above a specified level, the decision is made that a strip is in place.

While this approach has been used successfully on prior art meters, there are some drawbacks.

First, there are part to part variations in the sensor itself. The sensitivity of economical photo-reflective sensors is not tightly controlled. The manufacturer of the part can select parts to reduce the spread in sensitivity, but at an increased cost.

Second, there are meter to meter variations due to variations in the mounting of the part during manufacturing, and optical variations due to surrounding plastic parts

that can reflect some light toward the sensor. There is a limit to the uniformity of the manufactured optical assembly when all the components involved are considered.

Third, the threshold voltages of microprocessor inputs are frequently poorly specified. Even if the sensitivity variations cited are minimized, the threshold level and the part to part variability of ordinary microprocessor inputs are not often known with precision. Accurate thresholding circuitry can be added, but at additional cost.

Fourth, other component tolerances add variability to the sensitivity of the measurement. For example, tolerances on the current setting resistor for the device's LED, tolerance on the device's LED forward voltage, and tolerance on the device's output load resistor all add further variability to the system's sensitivity. In addition, the current setting voltage supplied by a microprocessor output can contribute additional variability.

Fifth, Standard Strips generate some reflectance signal, but must not be detected as a chemistry strip. Standard Strip tests are discussed further in commonly assigned copending US Patent Application No. 09/____,____ (Atty Dockey 0008-00000 entitled "Distinguishing Test Types Through Spectral Analysis"), filed concurrently herewith, the contents of which are incorporated herein by reference. During a Standard Strip test, a small portion of the standard strip will normally be within the field of view of the strip sensor and will generate a small amount of current due the light reflected from it. This condition, while small, will decrease the margin of error slightly for a fixed threshold case.

7

Sixth, ambient light leakage into the sensor that cannot be distinguished from light reflected from an inserted strip. Sunlight and light from interior lighting can reach the strip sensor and cause the sensor to produce a current that adds to the current produced by light reflected from a standard strip, a partially inserted test strip, or in combination with other internal reflectances. This can cause a false determination that a strip is in place. Tightening the tolerances in the plastic parts and altering the color and transmittance of the plastic parts can manage light leaks, but this adds a burden to the mechanical design and increases cost. Increasing the light that is used to make the reflectance measurement has reduced this sensitivity to bright ambient light somewhat in prior art meters, but the additional current required reduces battery life.

These drawbacks reduce the confidence that a simple fixed voltage level will always correctly identify that a strip is in place. Accordingly, it is an object of the present invention to provide an improved method for accurately detecting when a test strip has been inserted into the meter.

SUMMARY OF THE INVENTION

In accordance with the invention, a method is described for calibrating a strip sensor in an analytical meter device, the strip sensor having a photodetector and a light source, the method comprising the steps of: a.) measuring the voltage output difference of said photodetector between when said light source is on and off using a standard having relatively high reflectance; b.) measuring the voltage output difference of said photodetector between when said light source is on and off using a standard having relatively low reflectance; c.) calculating a voltage threshold V_{TH} produced by the strip

8

sensor to be used by said analytical meter device to indicate when a test element has been inserted therein according to the formula:

$$V_{TH} = K_{TH} [(V_{High} - V_{High\_Off}) - (V_{Low} - V_{Low\_Off})] + (V_{Low} - V_{Low\_Off})$$

where K_{TH} is a constant; d.) evaluating the value of V_{TH} calculated in step (c) for acceptability according to predetermined criteria; and e.) permanently storing V_{TH} in said analytical meter device if evaluated as acceptable in step (d).

The present invention advantageously allows the use of lower cost strip sensor devices, without compromising performance. According to one aspect of the invention, the sensitivity of each device is measured during factory calibration and a threshold calculated for each individual device. Thus, a much broader spread of sensitivities in strip sensors can be accommodated without increasing the risk of the meter making erroneous strip insertion decisions.

The present invention also provides improved confidence that erroneous strip detection will not occur. According to another aspect of the invention, the complete strip sensor system has its sensitivity measured during calibration. Thus, there is less risk of making erroneous strip insertion decisions due to normal variations in manufacturing tolerances of other components in the system and due to variation in the assembly of the system.

The present invention also provides improved performance in varying ambient light conditions. According to another aspect of the invention, the sensor's signal due to

9

ambient background light is measured prior to each normal reading and this signal is

accounted for separately from the signal due to reflection from an inserted strip. Thus,

the likelihood that excessive ambient light will cause an erroneous strip insertion

decision is reduced. Because of the highly improved light immunity, greater flexibility is

afforded to the mechanical and industrial design.

The present invention also provides additional checks to ensure that testing is

not performed in excessive ambient lighting conditions. According to yet another aspect

of the invention, these ambient checks add one more layer of assurance that a

chemistry test will not be performed under lighting conditions that could cause errors.

These checks allow the meter to adapt to changing ambient lighting conditions.

Additional objects and advantages of the invention will be set forth in part in the

description which follows, and in part will be obvious from the description, or may be

learned by practice of the invention. The objects and advantages of the invention will

be realized and attained by means of the elements and combinations particularly

pointed out in the appended claims.

It is to be understood that both the foregoing general description and the

following detailed description are exemplary and explanatory only and are not restrictive

of the invention, as claimed.

10

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of this specification, describe an illustrative embodiment of the invention and together with the description, serve to explain the principles of the invention.

Fig. 1 is a perspective view of an analyte meter system according to an illustrative embodiment of the present invention;

Fig. 2 is a test strip for receiving test fluid according to an illustrative embodiment of the present invention;

Fig. 3 is a schematic representation of a meter system according to the present invention.

DESCRIPTION OF AN ILLUSTRATIVE EMBODIMENT

Reference will now be made in detail to an illustrative embodiment of the invention, an example of which appears in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

With reference to the drawings, Fig. 1 depicts an analyte meter system 10 according to the present invention. Meter system 10 generally includes a hand-held meter having a housing enclosure 12, power switch/button 14, up/down menu navigation button 15, menu select button 17, liquid crystal display (LCD) 18, and removable test chamber cover or shroud 16 having a test strip platform 20 for receiving and testing a multi-layered diagnostic test strip 40 for the amount of a suspected analyte, such as glucose, cholesterol, ketones, theophylline, fructosamine, and others.

11

A strip sensor (not shown) of known configuration is located at a distal end of the strip platform 20 to detect when a test strip 40 has been fully inserted into the device. Although the discussion is directed herein to an illustrative embodiment of monitoring glucose levels in whole blood samples for purposes of describing the instant invention, one having ordinary skill in the art will appreciate that the present invention is adaptable for testing any of a plurality of analytes.

Fig. 2 illustrates an enlarged view of a representative diagnostic test strip 40. Test strip 40 generally includes an upper and lower support layer 41, 42, with sample receiving layers 50 located between the support layers. Sample receiving layers 50 include a spreading layer 47 located adjacent upper support layer 41, a separating layer 48, and a semi-porous membrane reagent layer 49 located adjacent lower support layer 42. At least one of the sample receiving layers 50 is pretreated with a dry chemistry reagent and conditioning solution. Preferably, the membrane 49 and separating layer 48 are pretreated with the reagent/conditioning solution. The spreading layer 47 may also be treated. Each layer is positioned in substantially continuous contact with its adjacent layer as shown in Fig. 2 by adhesives and ultrasonic bonding or other known means to provide a sealed composite structure.

The top and bottom support layers 41, 42 of test strip 40 each define an aperture or opening therethrough. These apertures or openings of the test strip are oriented in vertical alignment with test window of the meter (not shown) located along the strip platform, when properly positioned in meter system 10. The opening in the upper support strip 41 defines a sample receiving port 44a and the opening in the lower

12

support strip defines a reaction viewing port 44b. The sample receiving layers 50 are oriented in vertical alignment with sample receiving port 44a and reaction viewing port 44b. This allows the blood sample received by the strip to pass directly from receiving port 44a to viewing port 44b. As the sample travels to the viewing port 44b it will encounter reagent, and any analyte in the sample will begin to react with the reagent and begin to form a detectable condition, such as a color change. This detectable condition is assessed from the viewing port and can be used to determine the presence of, or to calculate the concentration of an analyte of interest. The test strip of Fig. 2 is illustrative only and many other test strip configurations may be used when practicing the present invention.

Monitoring meter system 10 of the present invention includes a circuit assembly physically and electrically connected to a printed circuit board, an example of which is schematically depicted as the block diagram of Fig. 3. The circuit 100 contains a microprocessor 102 with a plurality of inputs and outputs. An exemplary embodiment of the present invention uses an 8-bit device with 60K of programmable memory. The microprocessor executes the meter instruction code. The microprocessor receives input from the user through input device 104, which can include buttons or other input devices known in the art. A display 106 and a sounder 107 or similar output devices receives data from the microprocessor for presentation to the user. A memory device 108, for example EEPROM, is also connected for input from and output to the microprocessor 102. A communication port 110 can also connected in input-output relationship with the microprocessor in known manner.

13

A strip sensor 112 receives a drive signal through line 114 to turn on and off photo element 116. The photo element can be an LED. Light from the photo element 116 is detected by the photodetector 118. The photodetector can be a photodiode or phototransistor. Output from the photodetector is supplied via line 120 to the microprocessor 102. The strip sensor detects when a test strip is inserted into the meter.

The circuit assembly can include a light intensity control circuit, represented as section 122 of the diagram, and a light detector circuit 124, discussed in further detail hereinbelow. An exemplary embodiment of the present invention operates using a DC offset ("virtual ground") of 2.5V reference (not shown) and is powered from a 1.5V AAA battery (not shown), which may include a DC-DC converter circuit or other power management circuitry as is known in the art.

An analog to digital (A/D) converter 126 converts analog electrical output on line 128 from the light detector circuit 124 into digital information for the microprocessor 102. In an exemplary embodiment of the invention, a 12-bit A/D converter is employed. A temperature sensor 130 provides a voltage proportional to the temperature along line 132 to the A/D converter. The microprocessor 102 can make a determination as to whether the temperature of the testing environment is within predetermined levels, and prohibit a user from running a test if accuracy would be negatively affected.

The light intensity control circuit (LICC) 122 will now be described. In an exemplary embodiment, the circuit is supplied by a pulse width modulated signal along

14

line 134 from the microprocessor 102. The circuit includes a low pass filter 136, a modulator 137, a flux biasing resistor 138, a reference photodiode 140, a control loop error amplifier 142, a feedback loop compensation capacitor 144, and LED drive transistors 146. The LICC controls the drive supplied to the LEDs 148, as will be described.

The LEDs, of which there are two in the exemplary embodiment, generate light, a component 150 of which will encounter the target 152, which is the test strip or other test element inserted into the meter. Another component 154 of the light strikes a chamber reflector 156 and a portion of which 158 is reflected toward reference photodiode 140. One of the LEDs is a 660nm LED in the exemplary embodiment, which is appropriate for detecting glucose in a test strip marketed under the tradename PRESTIGE and sold by Home Diagnostics, Inc. of Ft. Lauderdale, FL. The exemplary embodiment can be easily modified for detecting other analytes or using other strips by changing the software and LED used to obtain a different wavelength. For instance, a 580nm LED would be preferred for ketones using known analytical chemistry systems.

The light detector circuit (LDC) 124 will now be described. In an exemplary embodiment, the LDC includes a main photodiode 160, a transimpedance (current to voltage) amplifier 162, a high pass filter 164, an amplifier 166, and a negative gain amplifier 168. The output stage of the exemplary LDC includes a demodulator 170, a level shifting amplifier 172, and a low pass filter 174. The output stage provides a DC voltage to line 128, as set forth above. The LDC supplies an analog signal to the A/D

converter, which when digitized is interpreted by the microprocessor to provide test results.

In the exemplary embodiment, input to the A/D converter is conventionally multiplexed, receiving input from lines 128 and 132, and from other signal lines not , shown and not necessary to understand the present invention.

In the exemplary embodiment, two LEDs are employed, at 610 nm and 660 nm as described herein. The LEDs are selected according to the instruction code at appropriate times by the microprocessor 102 by a signal sent via line 176, which activates a switch 178. If additional LEDs are employed, then additional signal lines and switches can be added in conventional manner. The selection between the two LEDs in the exemplary embodiment is the subject of commonly assigned copending US Patent Application 09/____,____ (Atty Docket 0008-00000 entitled "Distinguishing Test Types Through Spectral Analysis"), filed concurrently herewith, the contents of which are incorporated herein by reference.

The operation of the exemplary circuit 100 will now be described. A pulse width signal is produced by the microprocessor 102 along line 134. As is well known, the pulse width modulation signal is basically a 2.5V signal delivered either on or off according to a duty cycle. In a perfect square wave, the duty cycle is 50%, so that the signal is 50% on, and 50% off. Accordingly, when the signal is on, it is delivered at 2.5 volts and when it's off, it is zero volts. The signal in line 134 is averaged by the low pass filter 136 to arrive at a drive voltage for the LEDs, which will in turn determine their

16

output. For example, for a perfect 2.5V square wave, the average voltage, and thus the output of the low pass filter 136 will be 1.25V. In this way, the power delivered to the LEDs can be modified by the microprocessor by changing the duty cycle of the pulse width modulation signal. To increase the light power, the duty cycle of the signal would be increased.

In the exemplary embodiment, the duty cycle of the pulse width modulation signal is determined during factory calibration of the meter, and the duty cycle value is permanently stored in the EEPROM. Of course, periodic calibration routines known in the art could also be employed. Further, different LEDs may have different preferred drive requirements, so different duty cycles can be utilized based on the LED in operation.

The circuit 100 employs a modulation or "chopping" function controlled by the microprocessor 102. The microprocessor 102 supplies a modulation signal via line 180 to the modulator 137 of the LICC and to the demodulator 170 of the LDC in synchrony. The chopping signal is essentially a square wave (on/off) signal supplied to drive the LEDs at a certain frequency, rather than at constant power, to eliminate noise in the signal output of the circuit. In the exemplary embodiment, a 2048 Hz (approx. 2 kHz) chop is employed. The chopping function allows the shifting of the frequency of the light signals of the LICC upward to a "quieter" region of the spectrum where ambient light effects can be minimized in the LDC. For example, while sunlight is 0 Hz (DC), incandescent lights have a frequency of 120 Hz. Fluorescent lights are also 120 Hz, but

17

also have harmonic frequencies. By shifting the drive frequency of the LEDs above that of ambient light at the LICC, the LDC will be able to receive a signal at the matching frequency that is above the spectrum where most noise is encountered.

The LICC includes flux biasing resistor 138 which is in parallel with modulator 137. This resistor in parallel essentially inhibits the voltage from the low pass filter 136 from being completely turned off by the modulator 137. In this way, the chopping function, instead of modulating between full-on to full-off will modulate between full-on and low. The result is that the LEDs will be either full-on or dim, but never completely off. Several benefits are realized by this arrangement. First, because the LEDs are never dark, a positive bias is always present at the reference diode 140. As a result, when interfering ambient light reaches the reference diode 140, there is a tendency for the modulated signal to move toward ground. This positive bias helps to compensate for this tendency toward ground and allows the circuit to adapt without a change in peak-to-peak amplitude by keeping the modulated signal above ground. Second, the fact that a voltage is always present maintains control loop error amplifier 142 further above ground, which promotes better performance.

The control loop amplifier 142, in connection with the compensation capacitor 144 receives the output from the reference photodiode 140 to provide a feedback mechanism in determining the appropriate drive power for the LEDs 148.

When target 152 is illuminated by light 150 from an LED 148, reflected light 153 is received by the main photodiode 160, producing a photocurrent based on the

18

reflectance. The photocurrent output of the photodiode 160 is supplied to transimpedance amplifier 162, which converts the photocurrent to a voltage. This voltage is conditioned by high pass filter 164, which removes noise components of the signal below the chopping frequency. It is here that the noise components of artificial lighting are filtered out, although certain harmonics of fluorescent light are eliminated after demodulation by low pass filter 174. In the exemplary embodiment, a 400 Hz cutoff frequency is employed in high pass filter 164.

The signal emerging from high pass filter 164 is basically a square wave voltage at the chopping frequency. After amplification by amplifier 166, the square wave amplitude is nominally 0.5V peak-peak maximum and centered about the vitual ground of 2.5V. To condition the output for the A/D converter, which in the exemplary embodiment operates at approximately 2.6V maximum, amplifier 166 and negative gain amplifier 168 are employed as follows. When the LED is on, the top half of the square wave is connected by level shifting amplifier 172; and when the LED is off, the bottom half of the square wave is amplified by minus unity and connected by level shifting amplifier 172. This inverts the bottom half of the square wave when the LED is off. The demodulator 170 selects between the amplifiers 166, 168 in synchrony with the modulation occurring in the LIDC at modulator 137. The resulting signal emerging from demodulator 170 is a DC signal proportional to the reflectance of the chemistry, in relation to the 2.5V reference voltage in the exemplary embodiment.

19

Level shifting amplifier 172, a differential amplifier, receives the DC signal from the demodulator 170, applies a gain and shifts the signal to a range acceptable to the A/D converter, which in the exemplary embodiment is approximately 2.6V maximum. Low pass filter 174 removes spiking introduced by the demodulation of the signal by amplifiers 166, 168, and also removes a large amount of the harmonics of artificial light that were shifted high by the demodulation. Further, Any DC offsets in the amplifier stages prior to the demodulations that were shifted up to the chopping frequency are also effectively filtered. The only noise left in the signal are harmonics of ambient light that are right around the chopping frequency, which in the exemplary embodiment of 2 kHz are minimal.

These remaining harmonics are of known frequency and their relationship to the chop frequency will determine their frequency. For example, the 17th harmonic of fluorescent lighting will be 120Hz x 17 = 2040 Hz. If the chop frequency is 2048 HZ, which is more conveniently generated by binary digital systems than 2000Hz, the strongest remaining interfering harmonic will be 8 Hz (|2048Hz – 2040Hz|). Since this interfering signal is of known frequency, it can be further reduced by simple synchronous digital filtering techniques. In countries that use 50Hz power grids, the strongest interfering frequency will be 2 Hz (the 25th harmonic of 100Hz = 2050Hz, |2048Hz – 2050Hz| = 2Hz). A simple synchronous digital filtering technique that "nulls-out" both 2Hz and 8Hz can be implemented.

20

The microprocessor and code of instructions perform the calculations to arrive at the ultimate reported glucose measurement, for example as described in commonly assigned, copending US Patent Application No. 09/____,____, (Atty. Docket 0011-00000 entitled "Method for Determining the Concentration of an Analyte on a Test Strip") filed concurrently herewith, the contents of which have been incorporated herein by reference. It should be noted, however, that similar calculations can be used for deriving the amount of other analytes found in the fluid sample applied to the test strip so long as meter system 10 has been properly configured and calibrated for the particular test (analyte/reagent pair, etc.) of interest.

The instruction code includes a plurality of routines for operating meter system 10. The aspects of meter software include but are not limited to: meter power-up, system diagnostics, meter readying, meter calibration, reflectance and optics calibration, code curve calibration, strip sensor calibration according to the present invention, temperature calibration, the blood test algorithm, test strip code management, test results storage and recall, standard strip test management, operational mode management, and user preferences setup. With the exception of the blood test algorithm detailed below, the operational aspects of the software discussed above can be in any conventional format.

The blood test algorithm is initiated immediately upon the insertion of a test strip upon which fluid containing the analyte of interest has already been placed, and a reaction already underway. The insertion of a test strip 40 into the platform 20 trips a

strip sensor 112 as shown in Fig. 3 which comprises a phototransistor or photodiode that kicks off the blood test algorithm.

According to an illustrative embodiment of the present invention, the disadvantages of prior art strip insertion detection are solved through strip sensor calibration. During the normal manufacturing process of meters, the reflectometer (that is, the system that measures the reflectance of the diagnostic chemistry response) are calibrated using Standard Strips of known reflectance values. This combined with the additional ADC inputs now inexpensively available with new microprocessor designs provides an opportunity to calibrate the strip sensor.

A white calibrator, which is used to set the optical power in the reflectometer system, is configured so that when inserted into the meter it would trip the strip sensor and simulate a "Strip-In" condition. The strip sensor calibration process is as follows:

First, V_{SSW_OFF} and V_{SSW} are measured with the a white calibrator in place, where V_{SSW_OFF} and V_{SSW} are the strip sensor voltages with LED 116 off and on, respectively.

Second, V_{SSLG_OFF} and V_{SSLG} are measured with a light gray calibrator in place, where V_{SSLG_OFF} and V_{SSLG} are the strip sensor voltages with LED 116 off and on, respectively. The light gray calibrator in the exemplary embodiment is notched at its end so it does not cover the strip sensor. The light gray strip can be the same type of strip as the standard strip employed by the end user to verify the meter's calibration. When inserted, the standard strip must not be detected as a chemistry strip. The light gray calibrator with the notched end will produce a reference value for the "worst case" no-strip condition for which readings are still required from the main optics.

A threshold is then calculated according to the following equation:

$$V_{TH} = K_{TH} [(V_{SSW} - V_{SSW\_OFF}) - (V_{SSLG} - V_{SSLG\_OFF})] + (V_{SSLG} - V_{SSLG\_OFF})$$

Experimentally, it has been found that K_{TH} in the range of about 0.2 to 0.4 provides good results, with the exemplary embodiment using a value of 0.3.

If $(V_{SSLG} - V_{SSLG\_OFF}) / (V_{SSW} - V_{SSW\_OFF})$ is greater than a certain level, which for the exemplary embodiment of Fig. 3 has been determined experimentally to be about 0.35, it is determined that the calibration of the strip sensor has failed, and an error condition is indicated. This could transpire if the calibrator strips were not fully inserted during calibration or if the strip sensor's sensitivity is well above even the widened range specified by the manufacturer. If the calibration was properly run, then the strip sensor can be identified as defective and discarded.

If $(V_{SSLG} - V_{SSLG\_OFF}) / (V_{SSW} - V_{SSW\_OFF})$ is less than the threshold, then the calculated value of V_{TH} is determined to be acceptable, and is permanently stored in the meter. Each meter will have a uniquely calculated value for V_{TH} based on its actual performance during calibration stored in its memory.

According to a further illustrative embodiment, a technique known as Adaptive Thresholding may be employed. When using the strip sensor in normal operation, the ambient light as seen by the strip sensor is measured and the threshold calculated during calibration is added to this background level. The summed result is then used as the criterion for determining if a strip is in place.

23

The normal process for using the strip sensor is as follows:

First, V_{SS_OFF} is measured. This is the output of the strip sensor with its LED 116 turned off and represents therefore the ambient background level.

If $V_{SS\_OFF} + V_{TH}$ exceeds a threshold voltage, for example 3.0V for the exemplary embodiment shown in Fig. 3, a Fault Condition is indicated. This condition indicates that the output of the strip sensor for a strip-in condition will be above the maximum level that can be supplied by the strip sensor (*i.e.* the strip sensor will saturate for the strip-in condition).

Second, V_{SS} is measured. This is the output of the strip sensor with its LED 116 on and represents the light level due to the reflected light and the ambient light.

If $V_{SS} - V_{SS\_OFF} > V_{TH}$, then the strip is determined to be inserted.

The Fault Condition generated above due to excessive ambient light is defined by the meter firmware to be a "no-strip" condition. If there is no strip in place, that decision is correct. If there is a Standard Strip in the meter as described in commonly assigned copending Patent Application No. 09/____,____ (Atty. Docket 0008-00000 entitled "Distinguishing Test Types Through Spectral Analysis"), filed concurrently herewith, the decision is also correct. The opacity of the standard strip is high enough that a standard strip test can be done safely without the risk of the high light levels affecting the reflectometry.

If a chemistry strip is in place, this fault condition will cause the meter to refuse to detect the chemistry strip. This adds an additional measure of safety that a chemistry test will not be allowed in excessive ambient lighting conditions.

If this fault condition occurs after a chemistry test has initiated (due to changing ambient light conditions), the firmware will react as though the strip was removed during the test and abort the test with an appropriate error message. This again adds an additional measure of safety that a chemistry test will not be allowed in excessive ambient lighting conditions.
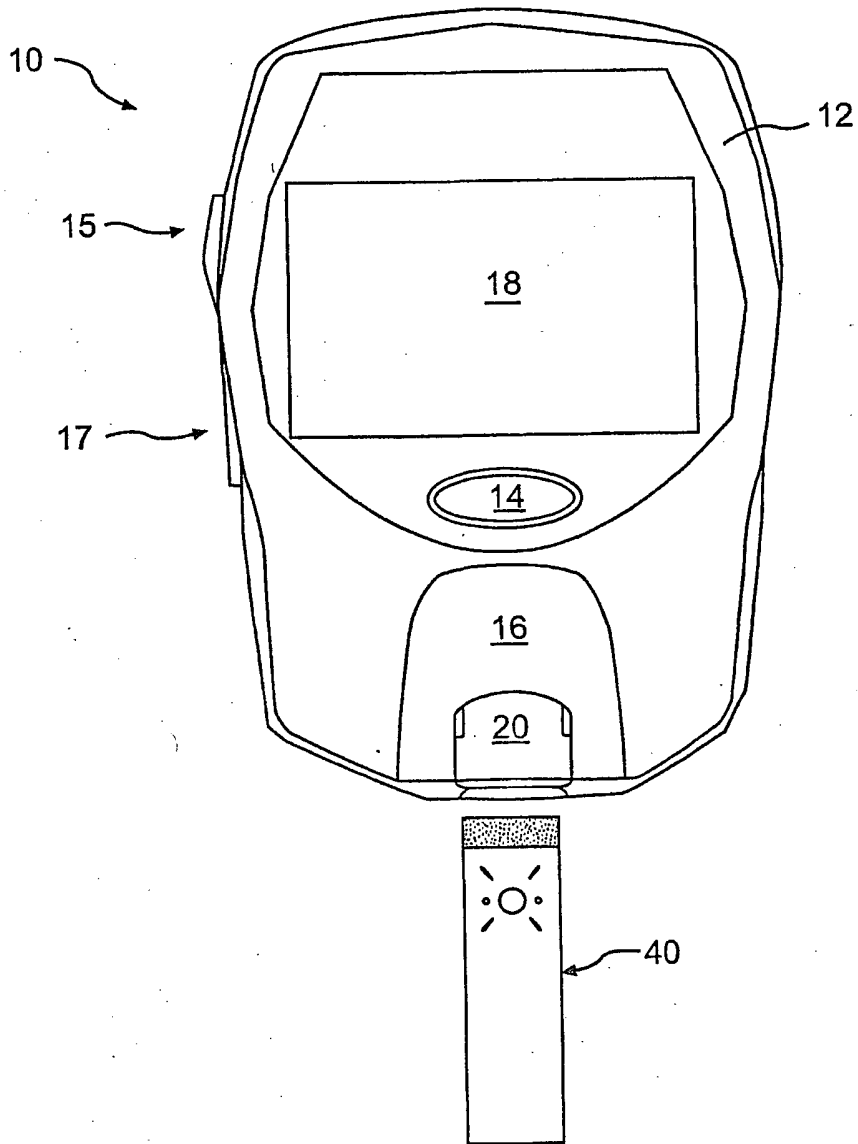
Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as illustrative only, with a true scope and spirit of the invention being indicated by the following claims.
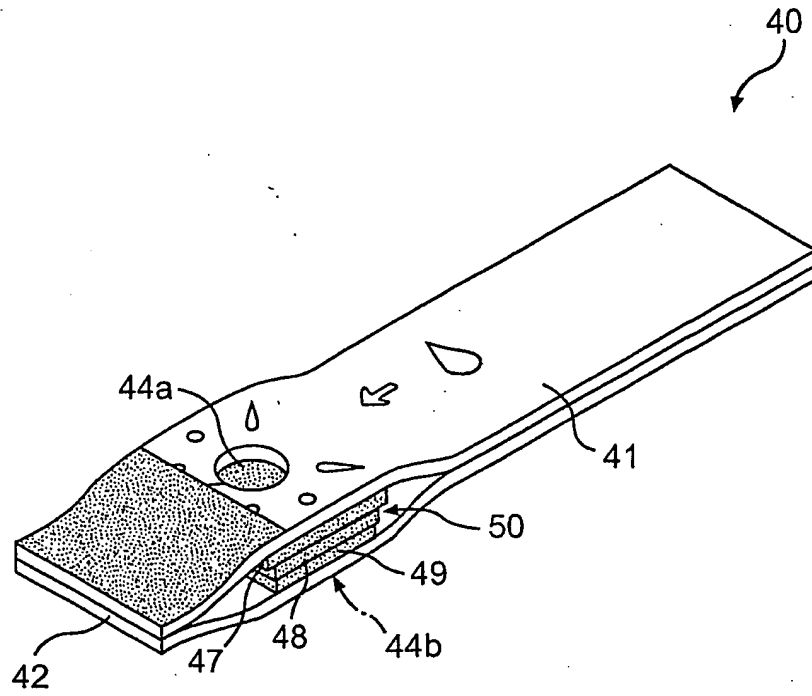
WE CLAIM:

1. A method for calibrating a strip sensor in an analytical meter device, the strip sensor having a photodetector and a light source, the method comprising the steps of:

    a. measuring the voltage output difference of said photodetector between when said light source is on and off using a standard having relatively high reflectance;

    b. measuring the voltage output difference of said photodetector between when said light source is on and off using a standard having relatively low reflectance;

    c. calculating a voltage threshold V_{TH} produced by the strip sensor to be used by said analytical meter device to indicate when a test element has been inserted therein according to the formula:

$$V_{TH} = K_{TH} [(V_{High} - V_{High\_Off}) - (V_{Low} - V_{Low\_Off})] + (V_{Low} - V_{Low\_Off})$$

    where K_{TH} is a constant;

    d. evaluating the value of V_{TH} calculated in step (c) for acceptability according to predetermined criteria;

    e. permanently storing V_{TH} in said analytical meter device if evaluated as acceptable in step (d).

2. The method of claim 1, wherein said standard of relatively high reflectance is a white calibrator.

3. The method of claim 1, wherein said standard of relatively low reflectance is a light grey calibrator.

4. The method of claim 1, wherein said value of K_{TH} is in the range of about 0.2 to 0.4.

26

5. A method of detecting a strip inserted into an analytical meter device calibrated according to the method of claim 1, wherein said method of detecting a strip comprises the step of monitoring said strip sensor for proximity of strip through adaptive thresholding.

6. The method of claim 5, wherein said step of monitoring further comprises the steps of:

   a. measuring the output of the photodetector with the light source turned off (V_{ss_OFF});

   b. comparing V_{ss_OFF} to a threshold voltage, and if V_{ss_OFF} is greater than said threshold voltage, indicating a fault condition;

   c. measuring the output of the photodetector with the light source turned on (V_{ss});

   d. determining a strip to be inserted if $V_{ss} - V_{ss\_OFF} > V_{TH}$.

7. A method of performing an analytical test on a strip inserted into an analytical meter device calibrated according to the method of claim 1, wherein said method of running an analytical test comprises the step of monitoring ambient light conditions with said strip sensor.

8. A method of performing an analytical test on a strip inserted into an analytical meter device calibrated according to the method of claim 5, wherein said method of running an analytical test comprises the step of monitoring ambient light conditions

27

by periodically repeating said step of monitoring said strip sensor for proximity of

strip.

9. A method of performing an analytical test on a strip inserted into an analytical meter

    device calibrated according to the method of claim 6, wherein said method of

    running an analytical test comprises the step of monitoring ambient light conditions

    by periodically repeating said step of monitoring said strip sensor for proximity of

    strip.

10. The method of claim 9, wherein said fault condition is determined by the analytic test

    device to indicate that there is no strip in place.

11. The method of claim 9, wherein said fault condition is determined by the analytic test

    device to indicate that there is a standard strip in place.

12. The method of claim 9, wherein said fault condition is determined by the analytic test

    device to indicate that there is a chemistry strip in place under adverse ambient

    lighting conditions.

13. The method of claim 12, wherein said fault condition is determined by the analytic

    test device after an analytical test has been started, and further comprising the step
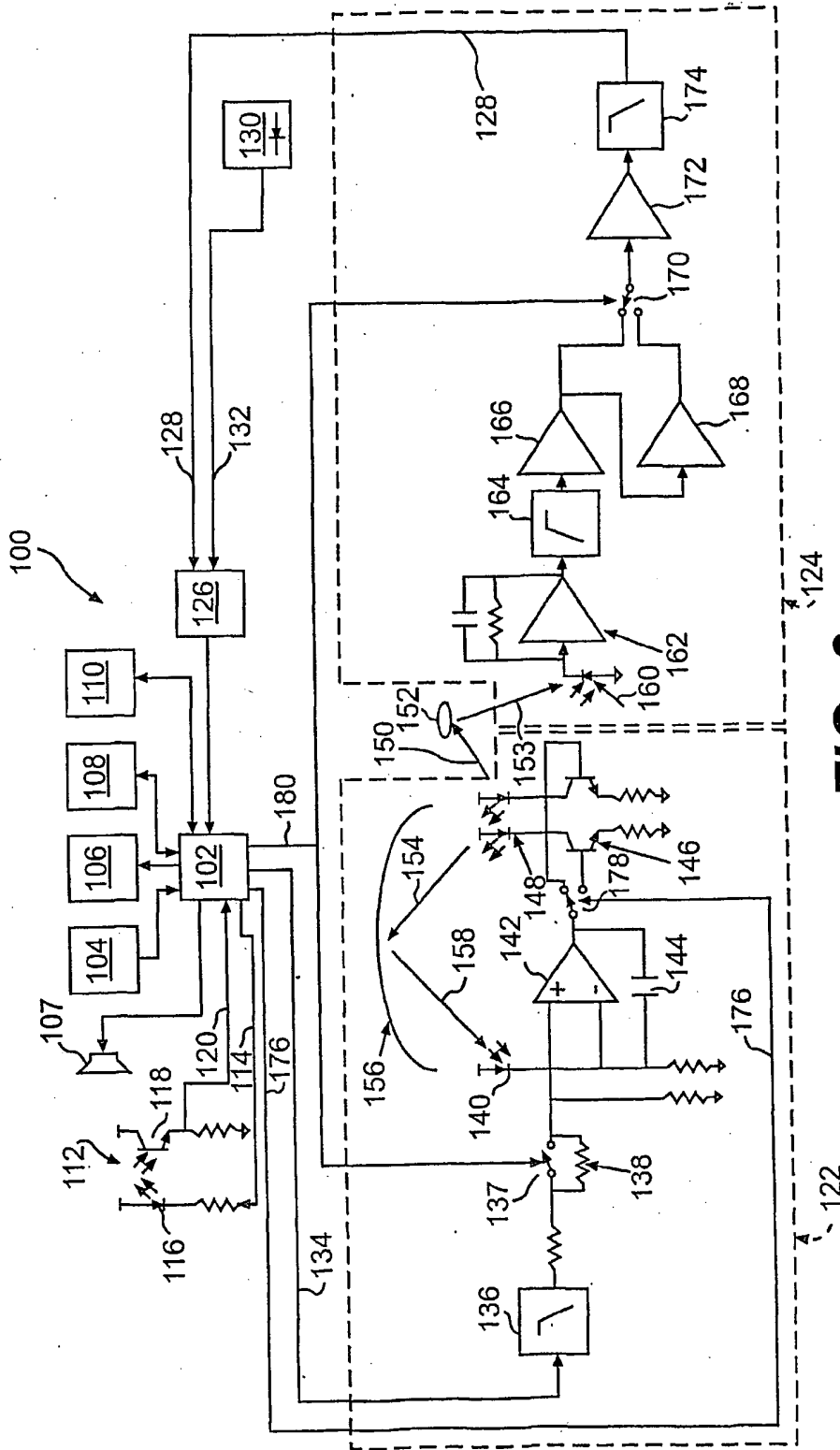
    of aborting the analytical test.

28

FIG. 1

40

44a

42

47   48   44b

50

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41

FIG. 2

FIG. 3